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10/597,172	09/10/2008	Richard Stuart Skipper	141.016US01	7091

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FOGG & POWERS LLC  
5810 W 78TH STREET  
SUITE 100  
MINNEAPOLIS, MN 55439

EXAMINER
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ROBITAILLE, JOHN P

ART UNIT	PAPER NUMBER
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1791

NOTIFICATION DATE	DELIVERY MODE
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09/11/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DAVID@FOGGLAW.COM  
docketing@fogglaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,172	<b>Applicant(s)</b> SKIPPER, RICHARD STUART	
	<b>Examiner</b> John P. Robitaille	<b>Art Unit</b> 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 27-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☒ Claim(s) 5 and 22 is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/05/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-26, drawn to a method of making contact lenses.

Group II, claim(s) 27, 43, drawn to a contact lens.

Group III, claim(s) 28-42, drawn to an apparatus for making contact lenses.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of groups I and II is a contact lens, disclosed in U.S. Patent 4,402,579.

3. The inventions listed as Groups I and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of groups I and II is a contact lens, disclosed in U.S. Patent 4,402,579.

4. The inventions listed as Groups II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of groups I and II is a contact lens, disclosed in U.S. Patent 4,402,579.

5. During a telephone conversation with Gregory Taylor on 24 July 2009 a provisional election was made with traverse to prosecute the invention of group I, claims 1-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Drawings***

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed features pertaining to packaging and inspection must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

7. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites all of the limitations of claim 10.

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Regarding claim 22, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 2, 5, 7-11, 13-16, 23, & 24 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al., '446 hereafter and already of record) in view of U.S. Patent 4,402,579 (Stanley Poler, '579 hereafter) and evidenced by Ichiro Sakurada (CRC Press; 1985; 9780824774349).

13. Regarding claim 1, '446 teaches a method of producing a plurality of soft contact lenses comprising the steps of: A. providing a sheet of solid, substantially dry material (C2L65-C2L68); C. hydrating said plurality of shaped lens blanks (C2L68)). '446 does not teach forming a plurality of blanks on the same sheet, or that the blanks remain attached to the sheet subsequent to formation.

14. In the same field of endeavor, formation of contact lenses, '579 teaches forming said material into a plurality of shaped lens blanks through controlled application of physical force to the material (C8L20-C8L25); and that at least immediately subsequently to said physical forming step B, said plurality of shaped lens blanks remain at least partially attached to the sheet of material for the benefit of easing mass production handling of the shaped lens blanks.

15. Regarding claim 2, '466 teaches a method of producing a plurality of soft contact lenses wherein said sheet of solid substantially dry solid material is water soluble above a certain temperature and formed into a plurality of shaped lens blanks at a temperature below said certain temperature (C7L9). Note that '446 teaches the use of poly(vinyl alcohol) and it is known in the art that poly(vinyl alcohol) is soluble in water above a

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certain temperature, as evidenced by "Polyvinyl alcohol fibers" by Ichiro Sakurada (CRC Press; 1985; 9780824774349) (see page 15).

16. Regarding claim 5, '446 teaches the method of producing a plurality of soft contact lenses in which the said material is chosen from the group consisting of polyvinyl alcohol or a copolymer of polyvinyl alcohol and polyvinyl acetate or polyethylene-maleic-anhydride or polymethyl-hydrox-propyl-cellulose or copolymers of methyl acrylate or ethyl acrylate or their derivatives (C7L9).

17. Regarding claim 7, '446 teaches a method of producing a plurality of soft contact lenses , in which said material is a substantially uncrosslinked polymer comprising crosslinkable groups and in which, prior to the hydration step C, high energy is applied to said plurality of shaped lens blanks, whereby said polymer is crosslinked to a predetermined, desired crosslink density (C6L30).

18. Regarding claim 8, '446 teaches a method of producing a plurality of soft contact lenses in which the material contains additives that react to the application of high energy to improve crosslinking efficiency (C5L64).

19. Regarding claim 9, '446 teaches a method of producing a plurality of soft contact lenses in which the application of high energy involves irradiation of the plurality of shaped lens blanks by a form of high energy chosen from the group consisting of electron beam irradiation or gamma irradiation or microwave irradiation or ultraviolet irradiation or infrared irradiation or thermal irradiation or ultrasound irradiation (C6L29).

20. Regarding claim 10, '446 teaches the method of producing a plurality of soft contact lenses wherein said material is provided in sheet form as addressed above.

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21. Regarding claim 11, '446 does not teach that the sheet material is used as a transport mechanism for the lens blanks.

22. In the same field of endeavor, contact lens manufacture, '579 teaches a method of producing a plurality of soft contact lenses in which the sheet is used as a transport medium or carrying mechanism for said plurality of shaped lens blanks (C4L45) for the benefit of transporting the lens blanks. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of '446 and '579 for the benefit of manufacturing lens blanks with a minimum of human intervention.

23. Regarding claim 13, '446 teaches a method of producing a plurality of soft contact lenses in which the physical forming step B is carried out using any one of the group of physical forming processes from the group consisting of thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding or injection moulding (C6L53).

24. Regarding claim 14, '446 teaches a method of producing a plurality of soft contact lenses in which said physical forming step B comprises the following substeps: B. 1 heating said material to a temperature that: a) is near to the softening temperature of the material, whereby thermoforming of said material is possible, but b) is below the melting point of said material, whereby the physical integrity of said material is maintained (C6L59); and B.2 thermoforming said plurality of shaped lens blanks through application of physical force to said material (C6L55).



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25. Regarding claim 15, '446 teaches a method of producing a plurality of soft contact lenses in which said thermoforming sub-step involves compression of the material between two forms or platens (C6L55).

26. Regarding claim 16, '446 teaches a method of producing a plurality of soft contact lenses, in which the physical forming step B involves the use of moulds and said material is placed between said moulds which are pressed together to form said plurality of shaped lens blanks (C6L55).

27. Regarding claim 23, '446 teaches a method of producing a plurality of soft contact lenses, in which all process steps subsequent to step B are carried out without fresher human contact or handling. Note that '446 does not specifically recite any human intervention.

28. Regarding claim 24, '446 teaches a method of producing a plurality of soft contact lenses, which method is automated or semi-automated to run in a continuous or semi-continuous manner (ABSTRACT).

29. Claims 3 & 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as applied to claim 1 above, and further in view of Hassan et al. (Amjad, Zahid (ed); Water Soluble Polymers - Solution Properties and Applications; Springer – Verlag; 1998; pp 31-40)

30. Regarding claims 3 & 4, the previous art combination does not teach the solubility transition temperature of the polyvinyl alcohol.

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31. In the same field of endeavor, PVA manufacture, Hassan et al. teach a PVA composition with a solubility transition temperature of about 50 °C or about 65 °C (p31 – ABSTRACT) for the benefit of obviating the need for crosslinking agents, thus rendering the PVA suitable for use in medical applications. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination with Hassan et al., for the benefit of making a film suitable for use in a medical application.

32. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as applied to claim 1 above, and further in view of Iwaseya et al. (J MATER SCI 41 (2006) 1979–1982)

33. Regarding claim 6, '446 teaches a method of producing a plurality of soft contact lenses, in which said material is a copolymer of polyvinyl alcohol and polyvinyl acetate (C13L14). '446 does not disclose the degree of hydrolysis.

34. In the same field of endeavor, polyvinyl alcohol film production Iwaseya et al. teach a degree of hydrolysis of 96%mol (Figure 1), for the benefit of increasing the crystallinity. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination with Iwaseya et al. for the benefit of increasing the crystallinity of the film.

35. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as

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applied to claim 1 above, and further in view of U.S. Patent 4,652,721 (Miller et al., '721 hereafter and already of record).

36. Regarding claim 12, the previous art combination does not teach that the lens blanks are removed from the sheet by a laser device.

37. In the same field of endeavor, contact lens manufacture, '721 teaches method of producing a plurality of soft contact lenses wherein said plurality of shaped lens blanks are fully removed from the sheet at a stage after step B by the use of a laser cutting device (ABSTRACT) for the benefit of completing the lens blanks without mechanical milling. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination with '721 for the benefit of minimizing the handling of the lens blanks.

38. Claims 17 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as applied to claim 1 above, and further in view of U.S. Patent 5,166,528 (Thurston C. Le Va, '528 hereafter)

39. Regarding claim 17, the previous art combination does not teach the sterilization.

40. In the same field of endeavor, contact lens manufacture, '528 teaches the method of producing a plurality of soft contact lenses, in which high energy is applied to said plurality of shaped lens blanks and/or to said plurality of soft contact lenses in order to sterilise them (ABSTRACT) for the benefit of preventing infection. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the

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teachings of the previous art combination with '528 for the benefit of producing a medical device which will not cause infections.

41. Regarding claim 18, the previous art combination does not teach the type of high energy used to sterilize.

42. In the same field of endeavor, contact lens manufacture, '528 teaches a method of producing a plurality of soft contact lenses in which the application of high energy involves irradiation by a form of high energy chosen from the group consisting of electron beam irradiation or gamma irradiation or microwave irradiation or ultraviolet irradiation (ABSTRACT) for the reasons stated in the rejection of claim 17 above.

43. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as applied to claim 1 above, and further in view of U.S. Patent Application Publication 2004/0112008 (Voss et al., 04/008 hereafter).

44. Regarding claim 19, the previous art combination does not teach transfer to final packs.

45. In the same field of endeavor, contact lens manufacture, 04/008 teaches the transfer of the lens blanks to final packs (ABSTRACT) for the benefit of maintaining the lens blanks in sterile storage. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination with 04/008 for the benefit of maintaining individual lens blanks in sterile containers.

46. Claims 20 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler)

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as in view of U.S. Patent Application Publication 2004/0112008 (Voss et al., 04/008 hereafter) and further in view of U.S. Patent 6,474,465 (Egbert Jux, '465 hereafter).

47. Regarding claim 20, the previous art combination does not teach that the final packs are presterilized.

48. In the same field of endeavor, contact lens manufacture, '465 teaches that the final packs are sterilized prior to packaging the lens blanks (C2L4) for the benefit of maintaining the sterile field. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination with '465 for the benefit of preventing infection. Note that since the final packs of '465 receive a sterile solution, it is essential that the packages themselves be presterilized in order to maintain the sterility of the solution and the lens.

49. Regarding claim 21, the previous art combination does not teach a sterile solution for hydrating the lens blanks in the final packs.

50. In the same field of endeavor, contact lens manufacture, '465 teaches the addition of a sterile solution for hydrating the contact lens blanks (C2L4) for the benefit of maintaining the oxygen permeability of the contact lens product. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination and '465 for the benefit of providing the end user with a contact lens with good oxygen permeability.

51. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as

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applied to claim 1 above, and further in view of U.S. Patent 6,113,817

(Herbrechtsmeier et al., '817 hereafter)

52. Regarding claim 21, the previous art combination does not teach hydrolysis in the final package.

53. In the same field of endeavor, contact lens manufacture, '817 teaches hydrolysis of the lens blanks within the final package (C15L65) for the benefit of increasing the crosslinking of the lens blanks. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination and '817 for the benefit of speeding the manufacture of contact lens blanks by allowing crosslinking to continue outside of the manufacturing line.

54. Claims 25 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,786,446 (Hammar et al.) in view of U.S. Patent 4,402,579 (Stanley Poler) as applied to claim 1 above, and further in view of U.S. Patent Application Publication 2002/0163638 (Biel et al., 02/638 hereafter) .

55. Regarding claim 25, the previous art combination does not teach an optical inspection system.

56. In the same field of endeavor, contact lens manufacture, 02/638 teaches a method of producing a plurality of soft contact lenses which further involves quality control inspections on the shaped lens blanks only (ABSTRACT) for the benefit of reducing the delivery of defective contact lenses to end users. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the

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teachings of the previous art combination with 02/638 for the benefit of reducing the delivery of defective contact lenses to end users.

57. Regarding claim 26, the previous art combination does not teach an optical inspection system.

58. In the same field of endeavor, contact lens manufacture, 02/638 teaches a method of producing a plurality of soft contact lenses which further involves quality control inspections on the shaped lens blanks only (ABSTRACT) for the benefit of reducing the delivery of defective contact lenses to end users. It would have been obvious to a person of ordinary skill in the art at the time of invention to combine the teachings of the previous art combination with 02/638 for the benefit of reducing the delivery of defective contact lenses to end users.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Robitaille whose telephone number is (571) 270-7006. The examiner can normally be reached on Monday to Thursday from 8:00 AM to 4:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JPR

/Joseph S. Del Sole/  
Supervisory Patent Examiner, Art Unit 1791